UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF OHIO EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION

THIS DOCUMENT RELATES TO:

MDL No. 2804 Case No. 17-MD-2804 Judge Dan Aaron Polster

Track Seven

KROGER DEFENDANTS' MOTION TO EXCLUDE THE OPINIONS OF PLAINTIFF'S EXPERT WITNESS, JACK E. FINCHAM

Defendants The Kroger Co., Kroger Limited Partnership I, and Kroger Limited Partnership II (hereafter collectively referred to as "Kroger") hereby move this Court, pursuant to Federal Rule of Evidence 702, to prohibit Plaintiff, Montgomery County Board of County Commissioners, from presenting the testimony and opinions of Plaintiff's expert witness, Dr. Jack E. Fincham. As explained in the Memorandum of Support, incorporated herein, Dr. Fincham's opinions do not satisfy the reliability and relevance requirements of Federal Rule of Evidence 702 and *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993) and its progeny. Kroger respectfully requests that this Court exercise its gatekeeping function to strike these expert opinions and preclude Dr. Fincham from testifying at trial.

MEMORANDUM IN SUPPORT

I. BACKGROUND

A. The 2020 and 2021 State of Ohio Board of Pharmacy Pharmacist Workload Surveys

In July of 2020, the State of Ohio Board of Pharmacy ("SOBP") disseminated a voluntary workload survey to all pharmacists working in the State of Ohio. See State of Ohio Board of PHARMACY, 2020 Pharmacist Workload Survey (2021) (attached as "Exhibit A"). The intent of the survey was to "capture feedback on pharmacist working conditions in [Ohio]." Id. at 4. The SOBP Executive Director, Steven W. Schierholt, stated that the data from this survey would be used to inform discussions regarding pharmacist practice in the State. *Id.* In November of 2021, the SOBP's Pharmacist Workload Advisory Committee issued a follow up survey, which followed the same parameters as the first survey and gathered additional data regarding the working conditions of pharmacists in the State. See McNamee Dep. 133:2-19, November 3, 2022 (attached as "Exhibit B"); see also State of Ohio Board of Pharmacy, 2021 Pharmacist Workload Survey (2022) (attached as "Exhibit C"). Cameron McNamee, the Director of Policy and Communication for the SOBP, drafted the questions for the 2020 and 2021 Pharmacist Workload Surveys (collectively, the "Pharmacist Workload Surveys" or "Surveys") and provided the SOBP with a summary of the results. *Id.* at 27:24-28:3. In his deposition, Mr. McNamee stated that the SOBP did not consult any survey experts when creating the SOBP Workload Surveys and noted that he does not hold a degree or have any training in survey design. Id. at 214:12-216:17, 217:10-12, 240:10-23.

The SOBP sent email links for completing the 2020 and 2021 Pharmacist Workload Surveys to all pharmacists in the State of Ohio, informing the pharmacists that the surveys were voluntary to complete, and that all survey responses would remain anonymous. *Id.* at 133:12-

134:6. Both Surveys gave pharmacists the opportunity to provide their own, freeform comments regarding their thoughts on the survey and pharmacy workloads. *See* Exh. A at 34 (requesting pharmacists responding to the survey to provide "[a]ny additional comments on this topic that you think would be helpful to the [SOBP]"); Exh. C. at 95 ("Please provide additional comments about the survey or about your job/career as a pharmacist"). The SOBP disseminated links to the 2020 Pharmacist Workload Survey to 11,588 Ohio pharmacists and received 4,159 responses, resulting in a completion rate of 26.41%. Exh. A at 4. 14,759 Ohio pharmacists received the 2022 Pharmacist Workload Survey, 2,969 pharmacists responded, resulting in a completion rate of 20.11%. Exh. C at 2.

B. Dr. Ann J. Selzer

Dr. Ann J. Selzer is an experienced quantitative researcher, research analyst, and survey expert. Her company, Selzer & Company, which she founded over twenty-five years ago, has conducted hundreds of surveys for a diverse clientele in a wide variety of industry groups, including surveys and focus groups for a grocery store chain. *Evaluation of 2021 Pharmacist Workload Survey Conducted by the State of Ohio Board of Pharmacy* ("Selzer Rpt.") (attached as "Exhibit D") at 1. Dr. Selzer was retained as an expert witness by Kroger to analyze the usefulness of the 2021 OSBP Pharmacist Workload Survey in understanding the role of pharmacists and pharmacies in opioid abuse and diversion. *Id.* at 2.

Dr. Selzer concluded that the 2021 Pharmacist Workload Survey does not reflect a valid measurement of pharmacists' views of opioid misuse and diversion because there were no survey questions about opioids, patient requests for controlled substances, or pharmacists' procedures for dispensing controlled substances. *Id.* She also opined that, because of methodological flaws in how the 2021 Survey responses were tabulated, the 2021 Survey data is not generalizable beyond the

respondent pool. *Id.* at 2-3. These methodological concerns included the 2021 Survey's roughly 20% response rate, as well as the lack of explanation as to whether the data was adjusted to conform to known population parameters amongst pharmacists. Dr. Selzer as opined regarding the inability to generalize the results of the survey to all Ohio pharmacists or to Kroger pharmacists working in Ohio because the 2021 Survey "did not include any information about real-world parameters of licensed pharmacists working in Ohio beyond the raw count of how many there are." *Id.* at 12-13, 17-18.

C. Dr. Jack E. Fincham

Plaintiff retained Dr. Jack E. Fincham as an expert witness to also analyze the SOBP Pharmacist Workload Surveys and to respond to Dr Selzer's analysis of the 2021 SOBP Workload Survey. *Expert Report of Dr. Fincham* ("Fincham Rpt.") (attached as "Exhibit E") at 1. Dr. Fincham is a licensed pharmacist and currently serves as a Professor at the University of Arizona's Osher Lifelong Learning Institute. *Id.* His professional experience includes serving as a professor and administrator at various universities and Colleges of Pharmacy and Public Health and teaching courses related to the practice of pharmacy and pharmaceutical marketing within the U.S. healthcare system. *Id.* Dr. Fincham previously served as an expert witness in several cases over the last twenty years, but prior to Plaintiff retaining Dr. Fincham for this litigation, he has never been asked to analyze the validity or intent of a survey or questionnaire. *See* Fincham Dep. 12:23-13:8, May 24, 2023 ("Exhibit F").

Dr. Fincham disputes the majority of Dr. Selzer's opinions related to the 2021 Pharmacist Workload Survey, arguing that the 2021 Survey "collected sufficient and reliable information from those Ohio pharmacists working in large chain grocery store settings that, when placed in the context of the opioid epidemic, identify serious concerns about the safe and effective dispensing

of opioids...." Fincham Rpt. at 5. He also disputes Dr. Selzer's opinions concerning methodological flaws in the 2021 Survey, arguing that the response rate for pharmacists responding to the surveys was adequate and appropriate and that there were reasonable explanations for why the 2021 Survey had more respondents than the 2020 Survey. *Id.* at 10. Dr. Fincham further criticizes Dr. Selzer for allegedly failing to consider the purpose of the 2021 Survey and alleges that interpreting the survey results fell outside of Dr. Selzer's expertise because she "does not know enough about the relevant aspects of pharmacy operations, dispensing regulations, or opioid abuse and diversion to interpret the survey results." *Id.* at 11, 13.

II. LEGAL STANDARD

Fed. R. Evid. 702 serves as the foundation for the admissibility of expert testimony in federal courts and provides as follows:

If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

The Supreme Court set forth the standard for admissibility of expert testimony under Fed. R. Evid. 702 in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993) and *Kumho Tire Co. v. Carmichael*, 526 U.S. 137 (1999). Federal district court judges are to serve a "gatekeeping role," whereby the trial judge must ensure that all scientific testimony or evidence admitted is both *relevant* and *reliable*. *In re Welding Fume Prod. Liab. Litig.*, 2005 WL 1868046, at *3 (N.D. Ohio Aug. 8, 2005) (quoting *Daubert*, 509 U.S. 579 at 589) (emphasis added). This gatekeeping function "applies not just to 'scientific' testimony, but to 'all expert testimony,' including technical or other specialized testimony." *Kumho Tire Co.*, 526 U.S. 137 at 147.

Although there is no single criterion for determining whether a specific scientific methodology employed by an expert witness is reliable, the *Daubert* Court identified several factors that a court should consider when evaluating the validity of expert testimony, including: (1) whether the expert's theory or technique "can be (and has been) tested"; (2) "whether the technique or theory has been subjected to peer review and publication"; (3) "the known or potential rate of error" of a technique; (4) "the existence and maintenance of standards controlling the technique's operation"; and (5) whether there has been "general acceptance" of the theory or technique within the "relevant scientific community." *In re Whirlpool Corp. Front-Loading Washer Prod. Liab. Litig.*, 45 F. Supp. 3d 724, 731 (N.D. Ohio 2014) (quoting *Daubert*, 509 U.S. 579 at 593-94).

Ultimately, expert testimony is only admissible if it will be helpful to the fact finder. *Redmond v. United States*, 194 F.Supp.3d 606, 615 (E.D. Mich. 2016) (citing *Daubert*, 509 U.S. at 591-93). Expert testimony is not helpful when it is unreliable or irrelevant or "when it merely deals with a proposition that is not beyond the ken of common knowledge." *Hayden v. 2K Games, Inc.*, No. 1:17CV2635, 2022 WL 3585655, at *3 (N.D. Ohio Aug. 22, 2022) (quoting *Id.*). Finally, a district court "must continue to perform its gatekeeping role by ensuring that the actual testimony does not exceed the scope of the expert's expertise, which if not done can render testimony unreliable under Rule 702." *In re Welding Fume*, 2005 WL 1868046 at *5 (quoting *Wheeling Pittsburgh Steel Corp. v. Beelman River Terminals, Inc.*, 254 F.3d 706, 715 (8th Cir. 2001)).

III. ARGUMENT

- A. Dr. Fincham's Opinions that the Pharmacist Workload Surveys Were Designed to Provide Insight on Opioid Abuse and Diversion Are Unreliable.
 - i. <u>Dr. Fincham's Conflicting Opinions Concerning the Purpose of the Pharmacist Workload Surveys Renders His Opinions Unreliable</u>

Dr. Fincham's opines that the data resulting from the Pharmacist Workload Surveys, "when placed in the context of the opioid epidemic, identif[ies] serious concerns about the safe and effective dispensing of opioids..." Fincham Rpt. at 5. However, he also agreed with Dr. Selzer in that that the Pharmacist Workload Surveys did not purport to measure pharmacists concerns about opioids. Fincham Dep. 162:19-22.

The Advisory Committee Notes to Federal Rule of Evidence 702 state that "any step that renders the analysis unreliable . . . renders the expert's testimony inadmissible" and "[t]his is true whether the step completely changes a reliable methodology or merely misapplies that methodology." (quoting *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 745 (3d Cir. 1994)). Here, Dr. Fincham's contradictory opinions concerning the purpose and applicability of the Pharmacist Workload Surveys, which are central to addressing the concept of validity in survey research, render his opinions concerning the Pharmacist Workload Surveys unreliable.

The central thesis of Dr. Selzer's report is that the "[2021 Pharmacist Workload Survey] is not a *valid* test of pharmacists' opinions or attitudes on how their work is related to opioid abuse and diversion." Selzer Rpt. at 3 (emphasis added). Dr. Selzer notes that, in survey research, the concept of validity addresses "whether the results of the survey accurately answer the research questions at issue." *Id.* In the litigation context, surveys not conducted specifically in preparation for, or in response to, litigation may sometimes provide important information, but they frequently ask irrelevant questions, unrelated to the issue in controversy. *See* 1 Mod. Sci. Evidence § 7:6 (2022-2023 Edition). Plaintiff's primary claim against Kroger, or the main "issue in controversy" in this litigation, is that Kroger and the other Defendants have "created and maintained a public nuisance by marketing, distributing, dispensing, and selling opioids in ways that unreasonably interfere with the public health, welfare, and safety in Plaintiff's community." *See Plaintiff*

Montgomery County's Supplemental and Amended Allegations to Be Added to Short Form (Dkt. 3738) ("Amended Complaint") at 247, ¶ 773. However, the SOBP never stated that the Pharmacist Workload Surveys purported to provide any data regarding opioids or diversion of controlled substances.

Dr. Selzer also noted that the Surveys failed to include any questions about opioids or patient requests for controlled substances. *See* Selzer Rpt. at 4. In his deposition, Dr. Fincham also agreed that intent of the Surveys, as stated by the SOBP, was to "capture vital feedback on pharmacists' working conditions in the State," and Dr. Fincham acknowledged that none of the Surveys' questions addressed opioids and that the Surveys did not purport to measure pharmacists concerns about opioids. *See* Fincham Dep. 71:19-72:12, 76:1-12, 162:19-22. In his report, Dr. Fincham noted that he and Dr. Selzer both agree that the 2021 Pharmacist Workload Survey was "a valid attempt to understand workplace issues among licensed pharmacists working in Ohio." Fincham Rpt. at 9 (quoting Selzer Rpt. at 4). Therefore, the Pharmacist Workload Surveys' results were not intended to reflect Ohio pharmacists' opinions concerning prescription opioids or the diversion of controlled substances, which renders Dr. Fincham's opinions unreliable.

ii. <u>Dr. Fincham Failed to Analyze the Data from the Pharmacist Workload Surveys in Accordance with Accepted Statistical Principles</u>

Daubert's reliability threshold requires an expert to analyze survey data in accordance with accepted statistical principles. Navarro v. Procter & Gamble Co., No. 1:17-CV-406, 2021 WL 868586, at *15 (S.D. Ohio Mar. 8, 2021) (internal citations omitted). However, Dr. Fincham fails to provide any statistical analysis of the Pharmacist Workload Surveys' data in support of his assertion that the data "identif[ies] serious concerns about the safe and effective dispensing of opioids..." Fincham Rpt. at 5. He even criticizes Dr. Selzer's analysis for counting the number of times the pharmacist respondents used terms like "opioids" and "controlled substances" in their

comments to the 2021 Pharmacist Workload Survey, arguing that this is "not an appropriate method in analyzing the views of a group of licensed professionals such as pharmacists." Fincham Rpt. at 20. However, Dr. Fincham provides no statistical analysis of his own to support his assertion that the Surveys' data provides meaningful insights into Ohio pharmacists concerns related to opioids or the prevention of diversion of controlled substances. Dr. Fincham appears to base his assertions on his own expertise, noting that pharmacists, like himself, are "keenly aware they must protect patients and that the inherent danger of controlled substances, the regulatory guidance to address these dangers and the significant additional due diligence that pharmacist must perform to dispense controlled substances are linked to 'safe and effective' patient care for pharmacists." *Id.* at 14.

The U.S. Supreme Court held that "nothing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert." *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997). One of the reasons *ipse dixit* arguments fail the Daubert reliability test is because "there is no methodology to connect the expert's conclusion to the facts." *Navarro*, 2021 WL 868586, at *16 (S.D. Ohio Mar. 8, 2021). Here, Dr. Fincham provides no statistical analysis of the Pharmacist Workload Surveys' data to show any connection to the data and Ohio pharmacists' views concerning prescription opioids or diversion. Accordingly, the Court should exclude Dr. Fincham's opinions because he failed to analyze the Pharmacist Workload Surveys' data in accordance with accepted statistical principles.

¹ Dr. Fincham criticized Dr. Selzer for failing to include the search terms: "PDMP" or "OARRS" in her analysis, arguing that she is unfamiliar with these terms because she is not a pharmacist. *See* Fincham Rpt. at 15, n. 61. Dr. Fincham explains that "OARRS is Ohio's Prescription Monitoring Drug Program ('PDMP') and contains a patient's controlled substance dispensing history across all pharmacies." *Id.* However, a simple search of the 2021 Pharmacist Workload Survey comments reveals that the term, "OARRS", only appears in one comment, which is the comment Dr. Fincham cites in his report, and there were zero results for the term "PDMP".

- B. Dr. Fincham's Opinions Concerning the Methodology of the Pharmacist Workload Surveys Are Also Unreliable.
 - i. <u>Dr. Fincham Opinions Regarding the Generalizability of the Pharmacist Workload Surveys Are Unreliable and Unhelpful to the Trier of Fact</u>

Dr. Fincham provided contradictory responses in his report and during his deposition on whether the results of the Pharmacist Workload Surveys were generalizable to the entire population of Ohio pharmacists. Dr. Selzer indicates that the purpose of conducting any survey is to "use answers from relatively few members of the meaningful universe under study to reflect all who meet the criteria of that meaningful universe in the real world." Selzer Rpt. at 15. Courts also recognize that the selection of the proper universe is "one of the most important factors in assessing the validity of [a] survey." *Leelanau Wine Cellars, Ltd. V. Black & Red, Inc.*, 452 F.Supp.2d 772 (W. D. Mich. 2006). For a survey's results to be accurate and generalizable to an entire population, "[the survey] must use a sampling method that ensures the sample is representative of the entire population." *Hurt v. Com. Energy, Inc.*, No. 1:12-CV-00758, 2015 WL 410703, at *5 (N.D. Ohio Jan. 29, 2015) (referencing DIAMOND, REFERENCE GUIDE ON SURVEY RESEARCH, 2004 WL 48153, at 239–42).

Dr. Selzer correctly notes that the 2021 Pharmacist Workload Survey did not draw a sample, and instead, only solicited responses from Ohio pharmacists who met its criteria. *See* Selzer Rpt. at 15. Accordingly, Dr. Selzer concludes that, although the data provided by the survey may reflect the opinions of the pharmacists working in Ohio who completed the survey, the findings cannot be reliably generalized to the full population of licensed pharmacists working in Ohio. *Id.* at 18. In his deposition, Dr. Fincham agreed that the 2021 Survey results were not generalizable to the working conditions of all pharmacies in Ohio. *See* Fincham Dep. 120:12-121:7 ("The survey wasn't [meant] to do any kind of generalization"); and 149:22-150:7 (Dr. Fincham

stated that the purpose of the survey was not to extrapolate the survey results to all pharmacists in Ohio). However, in his report, Dr. Fincham argues the "[d]ata from the surveys indicates that pharmacists working in large chain grocery stores believe their employers' policies and procedures, workload tasks, metrics and staffing levels in their workplace impact patient safety," including pharmacists' ability to meet their regulatory responsibilities in dispensing prescription opioid medication. Fincham Rpt. at 30.

Although Dr. Fincham stated that the SOBP Workload Survey results were not generalizable to entire pharmacist population in Ohio, Dr. Fincham nonetheless attempts to draw conclusions from beyond the SOBP Workload Surveys' respondent pool about the beliefs of all pharmacists working in large chain grocery stores in Ohio. Dr. Fincham's efforts are logically inconsistent and, regardless, his opinions do nothing to assist the trier of fact in understanding anything about the working conditions of all Ohio pharmacists or Ohio pharmacists who work or have worked for Kroger.

IV. CONCLUSION

For the reasons stated above, Kroger respectfully requests that this Court exercise its gatekeeping role, under Fed. R. Evid. 702, and issue an Order *in limine* excluding the expert opinions of Dr. Jack E. Fincham and prohibiting Dr. Fincham from offering any of his expert opinions at trial.

Respectfully submitted,

The Kroger Co., Kroger Limited Partnership I, Kroger Limited Partnership II,

By Counsel,

s/Ronda L. Harvey

Ronda L. Harvey, Esq. (WVSB 6326)
Ashley Hardesty Odell, Esq. (WVSB 9380)
Fazal A. Shere, Esq. (WVSB 5433)
BOWLES RICE LLP
600 Quarrier Street
Charleston, West Virginia 25301
304-347-1100
rharvey@bowlesrice.com
ahardestyodell@bowlesrice.com
fshere@bowlesrice.com

Case: 1:17-md-02804-DAP Doc #: 5070 Filed: 06/14/23 13 of 13. PageID #: 614098

CERTIFICATE OF SERVICE

I, the undersigned, hereby certify that on June 14, 2023, the foregoing document was filed

with the Clerk of the Court by using the CM/ECF system, copies of which will be served on

counsel of record by the Court's CM/ECF system.

s/Ronda L. Harvey

Ronda L. Harvey, Esq. (WVSB 6326)